

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Viktor Menart et al.  
Patent Number: 7,906,109  
Issue Date: March 15, 2011  
Application No.: 10/583,157  
PCT Filing Date: December 22, 2004  
'371 Date: June 16, 2006  
Confirmation No.: 5099  
Title: Pharmaceutical Composition Comprising an Active Principal and Sulphobetaine  
Examiner: Woodward, Cherie Michelle  
Group Art Unit: 1647

PETITION FOR RECONSIDERATION  
OF REVISED PATENT TERM ADJUSTMENT

MAIL STOP PETITION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

Pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. § 1.705, Applicants hereby petition for reconsideration of the revised patent term adjustment ("PTA") indicated on the official grant document issued on March 15, 2011, U.S. Patent Number 7,906,109, from the above-identified U.S. Application Serial No. 10/583,157. Accompanying this Petition are the following:

- (1) The **Statement of Facts** required under 37 C.F.R. § 1.705(b)(2), which begins on page 2 of this paper; and

- (2) Copies of two terminal disclaimers filed in this application on June 18, 2009, such copies beginning after page 4 of this paper.<sup>1</sup>

### STATEMENT OF FACTS

As explained below, Applicants respectfully submit that the PTA should be 252 days. U.S. Patent Number 7,906,109, as issued on March 15, 2011, indicated a revised PTA of 197 days, as opposed to the original estimated PTA of 0 days. Applicants therefore have up to two months from the issue date of this patent to request reconsideration of this revised PTA under 37 CFR § 1.705. The specific facts given below show that the revised PTA is in error, and should actually be 252 days.

#### Information relevant to 37 C.F.R. § 1.705(b)(2)(i)

This requested revision is premised on what appears to be an incorrect calculation of the so-called “Part B” delay by the U.S.P.T.O., such delay being based on 37 C.F.R. § 1.702(b) (i.e., “the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f)”). Based on Applicants analysis, the proper Part B delay should be 300 days instead of 245 days as calculated by the U.S.P.T.O. in its *revised* patent term adjustment calculation.

#### Information relevant to 37 C.F.R. § 1.705(b)(2)(ii)

Applicants’ calculation is based on the difference between June 23, 2009 (i.e., 3 years after the filing date of Applicants’ application) and April 19, 2010, which is the date on which Applicants requested continued examination pursuant to 35 U.S.C. § 132(b), thereby cutting off any further Part B delay pursuant to 37 C.F.R. § 1.702(b)(1). These dates are based on the period of USPTO delay described in 37 C.F.R. § 1.703(b)(1).

Applicants agree with all other calculations made by the USPTO, including the “Part A” delay, the “Part C” delay, and the overlap between the Part A and Part B delay. Thus, the only difference in the revised patent term adjustment as calculated by the USPTO at patent issuance and

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<sup>1</sup> The Fee required for this Petition as set forth in § 1.18(e) pursuant to 37 C.F.R. § 1.705(b)(1) may be charged to deposit account number 12-2355.

May 13, 2011

the requested adjustment of the revised patent term adjustment by Applicants is 55 days (i.e., 300 days minus 245 days).

Information relevant to 37 C.F.R. § 1.705(b)(2)(iii)

This application is subject to two potential terminal disclaimers as set forth in the response filed on June 18, 2009, a copy of which is disclosed herein. The relevant dates of expiration, if any, are described therein.

Information relevant to 37 C.F.R. § 1.705(b)(2)(iii)

Applicants agree with the calculation made by the U.S.P.T.O. regarding any applicable delay of Applicants under 37 C.F.R. § 1.704, and do not dispute that such delays occurred. Even including such delays on the party of Applicants, however, including the filing of a request for continued examination pursuant to 35 U.S.C. 132(b) on April 19, 2010, there were still 300 days between April 19, 2010, and the date exactly three years after the filing date of the application. Thus, the Part B delay should be 300 days instead of 245 days, resulting in an overall revised patent term adjustment of 252 days.

Information relevant to 37 C.F.R. § 1.705(d)

This request is based on the revised patent term adjustment which was made *after* the issue fee was paid, and is therefore an issue that could not have been properly raised before paying the issue fee.

In light of the foregoing, the present petition is believed to be in full compliance with the requirements of 37 C.F.R. § 1.705, and to be well taken. In the event this response is not in full compliance with all applicable rules, Applicants hereby petition for any appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. **12-2355**.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /Mark S. Graham/

Mark S. Graham

Registration No. 32,355

MSG:MER:lal

Application No. 10/583,157  
May 13, 2011

Date: May 13, 2011

P.O. Box 1871  
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Applicant(s): Viktor Menart et al.  
Application No.: 10/583,157  
Filing Date: June 16, 2006  
Confirmation No.: 5099  
Title: A Pharmaceutical Composition Comprising an Active Principal and Sulphobetaine  
Examiner: Woodward, Cherie Michelle  
Group Art Unit: 1647

TERMINAL DISCLAIMER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

LEK Pharmaceuticals D.D. (hereinafter "LEK"), a Company organized under the laws of the Republic of Slovenia, having a place of business at Verovskova 57, 1526 Ljubljana, Slovenia, represents that it is the assignee and owner of the entire interest in the above-identified application by reason of an assignment executed by the inventors Viktor Menart, Vladka Gaberc Porekar, and Barbara Podobnik on May 4, 2006. This assignment was recorded in the U.S. Patent Office on January 19, 2009, at Reel / Frame Number 022124 / 0719.

LEK hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application which would extend beyond the expiration date of the full statutory term defined in 35 USC § 154 – 156 and § 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending Application No. 10 / 577,285, which is the U.S. national phase of PCT application PCT/IB03/05575, filed November 4, 2003. Said Application No. 10 / 577,285 is also assigned to LEK by reason of an

Application No. 10/583,157

assignment executed by the inventors Barbara Podobnik, Vladka Gaberc Porekar, and Viktor Menart on April 5, 2006. This assignment was recorded in the U.S. Patent Office on January 8, 2009, at Reel / Frame Number 022075 / 0515.

LEK hereby agrees that any patent granted on the above-identified application shall be enforceable only for and during such period that it and any patent granted on Application Number 10 / 577,285 are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, LEK does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 USC § 154 – 156 and § 173 of any patent granted on Application No. 10 / 577,285, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

A terminal disclaimer fee under 37 CFR § 1.20(d) is included.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /J. David Gonce/

J. David Gonce

Registration No. 47,601

Date: June 18, 2009  
P.O. Box 1871  
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Application No. 10/583,157

assignment executed by the inventors Viktor Menart on January 5, 2005; Simona Jevsevar on January 4, 2005, and Vladka Porekar on January 4, 2005. This assignment was recorded in the U.S. Patent Office on January 8, 2009, at Reel / Frame Number 022074 / 0946.

LEK hereby agrees that any patent granted on the above-identified application shall be enforceable only for and during such period that it and any patent granted on Application Number 10 / 522,826 are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, LEK does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 USC § 154 – 156 and § 173 of any patent granted on Application No. 10 / 522,826, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

A terminal disclaimer fee under 37 CFR § 1.20(d) is included.

Respectfully submitted,

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